

MAY 16 2011

**510(k) Summary****Submitter information**

<i>Company name</i>	Materialise N.V.
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<i>City</i>	Leuven
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<i>Contact name</i>	Alexandra Razzhivina
<i>Contact title</i>	Regulatory affairs officer
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**Submission date**

The date of the Traditional 510(k) submission is 11<sup>th</sup> of February.

**Submission information**

<i>Trade Name</i>	Signature™ Planner Signature™ guides
<i>Common Name</i>	Knee prosthesis
<i>Classification Name</i>	- Knee joint patellofemoral tibial polymer/metal/polymer semi-constrained cemented prosthesis - Knee joint patellofemoral tibial metal/polymer porous-coated uncemented prosthesis - Knee joint femoral tibial metal/polymer semi-constrained cemented prosthesis
<i>Product code</i>	JWH/OIY (21 CFR § 888.3560), MBH (21 CFR § 888.3565), HRY (21 CFR § 888.3530), OOG

**Predicate devices**

<b>Predicate Device</b>	
<i>Trade or proprietary or model name</i>	Signature™ Personalized Patient Care System
<i>510(k) number</i>	K102795
<i>Decision date</i>	02/02/2011
<i>Product code</i>	JWH/OIY, MBH, OOG
<i>Manufacturer</i>	Materialise N.V.

<b>Predicate Device</b>	
<i>Trade or proprietary or model name</i>	Patient Matched Cutting Blocks
<i>510(k) number</i>	K082358
<i>Decision date</i>	11/25/2008
<i>Product code</i>	JWH, MBH
<i>Manufacturer</i>	Smith and Nephew, Inc.

## ***Device Information***

### **Description of the device**

The **Signature™ Personalized Patient Care System** consists of a software component, **Signature™ Planner** and a hardware component, **Signature™ guides** and is designed to assist the surgeon in the placement of Biomet total and partial knee replacement components.

### **Functioning of the device**

The **Signature™ Personalized Patient Care System** generates a pre-surgical plan based on MRI imaging data using the **Signature™ Planner** (software component). The software is then used pre-operatively by a qualified surgeon to inspect, fine-tune and approve the pre-surgical plan. Next, **Signature™ guides** are designed and manufactured based on the approved pre-surgical plan. **Signature™ guides** are patient specific templates that transfer the pre-operatively determined cut planes for positioning of the total and partial knee replacement components to the patient intra-operatively, assisting the surgeon in positioning and aligning the actual total and partial knee replacement components by guiding and marking drill and/or cut locations.

### **Intended use**

**Signature™ Personalized Patient Care System** is intended to be used as a surgical instrument to assist in the positioning of total and partial knee replacement components intra-operatively and in guiding the marking of bone before cutting and to guide cutting, provided that anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient imaging scans.

The **Signature Personalized Patient Care System** can be used with the following Biomet® Knee Systems and their respective components: Vanguard™ Complete Knee System, Vanguard™ M Unicompartmental Knee System, Vanguard™ SSK 360, Vanguard™ SSK Revision Knee System, Regenerex™ Primary Tibial System, Offset & Microplasty Tibial Systems, Maxim™ Complete Knee System, Ascent™ Total Knee System, and AGC™ Complete Knee system.

The **Signature™ guides** are intended for single use only.

### **Summary of technological characteristics**

Device comparison showed that the proposed device is substantially equivalent in intended use, materials and performance characteristics to the predicate devices.

### **Performance data**

#### **Non-clinical tests**

The **Signature™ Planner** software has been validated for its intended use to determine substantial equivalence to the predicate devices.

Accuracy performance testing by means of cadaveric trials, and guide deformation verification after sterilization was performed to determine substantial equivalence. Testing

verified that the accuracy and performance of the system is adequate to perform as intended.

**Clinical data**

Not applicable.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room -WO66-G609  
Silver Spring, MD 20993-0002

Materialise N.V.  
% Ms. Alexandra Razzhivina  
Technologielaan 15  
3001 Leuven  
Belgium

MAY 16 2011

Re: K110415  
Trade/Device Name: Signature guides™, Signature™ Planner  
Regulation Number: 21 CFR 888.3530  
Regulation Name: Knee joint femorotibial metal/polymer semi-constrained cemented  
prosthesis  
Regulatory Class: Class II  
Product Code: HRY, JWH, OIY, MBH, OOG  
Dated: May 4, 2011  
Received: May 6, 2011

Dear Ms. Razzhivina:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Mark N. Melkerson' with a stylized flourish at the end.

Mark N. Melkerson

Director

Division of Surgical, Orthopedic,  
and Restorative Devices

Office of Device Evaluation

Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K110415

**Device Name:** The Signature™ Personalized Patient Care System (Signature™ guides, Signature™ Planner)

### Indications for Use:

Signature™ Personalized Patient Care System is intended to be used as a surgical instrument to assist in the positioning of total and partial knee replacement components intra-operatively and in guiding the marking of bone before cutting and to guide cutting, provided that anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient imaging scans.

The Signature™ Personalized Patient Care System can be used with the following Biomet® Knee Systems and their respective components: Vanguard™ Complete Knee System, Vanguard™ M Unicompartmental Knee System, Vanguard™ SSK 360, Vanguard™ SSK Revision Knee System, Regenerex™ Primary Tibial System, Offset & Microplasty Tibial Systems, Maxim™ Complete Knee System, Ascent™ Total Knee System, and AGC™ Complete Knee system.

The Signature™ guides are intended for single use only.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

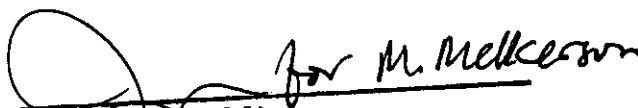
AND/OR

Over-The-Counter Use         
(21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)  
Division of Surgical, Orthopedic,  
and Restorative Devices

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